6-24-05 IFW

Docket 17328CON4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Aoki et al.	Examiner: C. Kam
Serial Number: 10/630,206	Art Unit: 1653
Filed: July 29, 2003	
For: TREATMENT OF A FACIAL PAIN BY PERIPHERAL ADMINISTRATION OF A NEUROTOXIN	Irvine, California

RESPONSE TO OFFICE ACTION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This response amends the title on page one of the specification, amends claims 1, 12, and 31-32, and cancels claims 28-30. See pages 13-20 of this response.

I. The Office Action

The May 9, 2005 non-final office action (the "Office Action") in this application:

1. rejected claims 1, 4, 5, and 9 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent 6,113,915.

2. provisionally rejected claims 1, 4, 5, 9, 12, 13, and 28-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9, 12, 13 and 28-34 of co-pending application 10/630,204.

3. provisionally rejected claims 1, 4, 5, 9, 12, 13, and 28-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of co-pending application 11/003,677.

4. rejected claims 1, 4, 5, 9, 12, 13, and 28-32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the claims are alleged to be indefinite because of a lack of essential steps in the method for treating pain, where the omitted steps are stated to be the effective amount of a botulinum toxin used and/or the outcome of the treatment.

5. rejected claim 9 as indefinite because of the use of the term "substantially alleviated".

6. rejected claim 32 as indefinite because the claim is dependent from a non-existing claim, claim 33.

7. rejected claims 1, 4, 5, 9, 12, 13, 28, 31, and 32 under 35 U.S.C. 102(b) as anticipated by Binder (WO 95/30431).

8. rejected claims 1, 4, 5, 9, 12, 13 and 28-32 under 35 U.S.C. 102(b) as being anticipated by Aoki et al. (WO 95/17904).

9. rejected claims 1, 4, 5, 9, 12, 13 and 28-32 under 35 U.S.C. 102(e) as anticipated by First (U.S. Patent 6,063,768.

Applicants respond to the Office Action as follows.

II. Obviousness-Type Double Patenting.

The Office Action rejected claims 1, 4, 5, and 9 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent 6,113,915.

Claims 1-12 of U.S. Patent 6,113,915 disclose a method for treating pain, comprising **intraspinal** administration of a therapeutically effective amount of botulinum toxin to a mammal. The Office Action states that claims 1-12 of U.S. Patent 6,113,915 and claims 1, 4, 5, and 9 of this application both "cite a method of treating pain such as joint pain, comprising administration (e.g., intraspinal administration) of a botulinum toxin."

Applicant has amended claim 1 to overcome the objection.

Thus, claim 1 has been amended to clarify that the "administration of a botulinum toxin to a mammal" is a **"peripheral"** administration. The amendment is supported by the specification at at least page 1, lines 11-13; page 20, lines 3-4; and at page 29, lines 27-29.

Furthermore, note that peripheral administration is defined on page 25, lines 21-26 of this application to specifically exclude any direct administration to the central nervous system. Contrarily, claims 1-12 of U.S. Patent 6,113,915 are limited specifically to intraspinal administration (see e.g. claim 1). Furthermore, in column 10, lines 26-29 of U.S. Patent 6,113,915 **intraspinal is limited** to the epidural space, the intrathecal space, the white or gray matter of the spinal cord or affiliated structures such as the dorsal root and dorsal root ganglia. It is understood by those skilled in the art that the enumerated structures are a part of the central nervous system and are not amenable to the claimed "peripheral administration".

Thus, the claim as amended does not add any new matter and for reasons set forth above withdrawal of obviousness-type double patenting over U.S. Patent 6,113,915 is requested.

III. Terminal Disclaimers

1. Co-pending application 10/630,204.

The Office Action provisionally rejected claims 1, 4, 5, 9, 12, 13, and 28-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9, 12, 13 and 28-34 of co-pending application 10/630,204.

While applicant dos not agree that claims 1, 4, 5, 9, 12, 13, and 28-32 are unpatentable over claims 1, 4, 5, 9, 12, 13 and 28-34 of co-pending application 10/630,204 due to obviousness-type double patenting, a terminal disclaimer is enclosed to obviate this rejection and thereby expedite prosecution of this application.

2. Co-pending application 11/003,677.

The Office Action provisionally rejected claims 1, 4, 5, 9, 12, 13, and 28-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of co-pending application 11/003,677.

While applicant does not agree that claims 1, 4, 5, 9, 12, 13, and 28-32 are unpatentable over claim 1 of co-pending application 11/003,677 due to obviousness-type double patenting, a terminal disclaimer is enclosed to obviate this rejection and thereby expedite prosecution of this application.

Therefore, withdrawal of the rejection is requested.

III. 35 U.S.C. 112(2) Rejection.

1. Lack of essential steps.

The Office Action rejected claims 1, 4, 5, 9, 12, 13, and 28-32 under 35 U.S.C. 112, second paragraph, as being indefinite because the claims allegedly lack the essential steps of an effective amount of a botulinum toxin used and/or the outcome of the treatment.

While applicant does not agree with the rejection, applicant has amended independent claims 1, 12, and 31 to add the limitation "therapeutically effective amount of." This amendment to the claims is supported by at least page 34, lines 2-3 of the specification.

Applicant has also amended claims 1 and 31 to add the limitation "thereby alleviating the face pain." This amendment to the claims is supported by at least page 43, lines 5-14 of the specification.

The claims have been amended to provide the steps that were stated to be missing. Therefore, withdrawal of the rejection is requested.

2. Indefiniteness Rejection.

The Office Action rejected claim 9 as indefinite because the use of the term "substantially alleviated" is not clear to what extent the pain is alleviated.

Applicant has deleted "substantially" from the claim.

The claim as amended overcomes the rejection, therefore, withdrawal of the rejection is requested.

3. Indefiniteness Rejection – Improper Dependent Claim

The Office Action rejected claim 32 as indefinite because the claim is dependent from a non-existing claim, claim 33.

Applicant has amended claim 32 so as to be dependent from claim 31.

The claim as amended overcomes the rejection, therefore, withdrawal of the rejection is requested.

IV. 35 U.S.C. 102 Rejections

1. 35 U.S.C. 102(b) Rejection as Anticipated by Binder (WO 95/30431)

The Office Action rejected claims 1, 4, 5, 9, 12, 13, 28, 31, and 32 under 35 U.S.C. 102(b) as anticipated by Binder (WO 95/30431).

Since claim 29 was not rejected as being anticipated by Binder, Applicant has amended independent claims 1, 12 and 31 to incorporate all the limitations of claim 29, thereby overcoming the rejection. Therefore, withdrawal of the rejection is requested.

Applicant hereby cancels claims 28-30 without prejudice to further prosecution at a later date.

2. 35 U.S.C. 102(b) Rejection as Anticipated by Aoki et al. (WO 95/17904)

The Office Action rejected claims 1, 4, 5, 9, 12, 13 and 28-32 under 35 U.S.C. 102(b) as being anticipated by Aoki et al. (WO 95/17904). The Aoki et al. reference discloses methods for treating pain related to "muscle activity" or "contracture" (see page 1, lines 9-16 and page 4, line 29 through page 5, line 7 of Aoki et al.)

Contrarily, all claims in this application have been amended to limit the claims to treatment of pain which is not related to muscle activity or contractures. Thus, all claims have been amended to add the limitation "wherein the face pain is not associated with a muscle disorder."

This limitation is supported by the specification at least as follows: page 19, line 22 through page 20, line 1 and page 20, lines 4-8.

Since Aoki et al. teach only methods for relieving pain associated with muscular contractions and/or spasms, and all claims in the present application are limited to methods for treating pain unrelated to muscular contractions and/or spasms, the present claims are therefore not anticipated by Aoki et al.

The claims as amended do not introduce any new matter. For the reasons set forth above, withdrawal of the rejection is requested.

3. 35 U.S.C. 102(e) Rejection as Anticipated by First (U.S. Patent 6,063,768)

The Office Action rejected claims 1, 4, 5, 9, 12, 13 and 28-32 under 35 U.S.C. 102(e) as anticipated by First (U.S. Patent 6,063,768, filing date September 4, 1997). First discloses methods for treating neurogenic inflammatory disorders. However, First does not teach or suggest treatment of a pain in the face.

Thus, claims 1, 12, and 31 have been amended to treat "a face pain." This limitation is supported by the specification at at least page 43, lines 5-14.

The claims as amended do not introduce any new matter. For the reasons set forth above, withdrawal of the rejection is requested.

V. Amendment to Page One of the Specification

The title of the application has been amended to provide a title more descriptive of the claimed subject matter.

Thus, applicant has changed the title from: "Pain Treatment by Peripheral Administration of a Neurotoxin"

to: "Treatment of a Facial Pain by Peripheral Administration of a Neurotoxin."

The amended title is supported by at least page 43, lines 5-14 of the specification.

VI. Conclusion

All issues presented by the examiner have been addressed. Examination and allowance of claims 1, 4, 5, 9, 12, 13, and 31-32 is requested.

Respectfully submitted,

Date: June 22, 2005

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CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10

I hereby certify that this Transmittal Letter, Response to Office Action and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date **June 22, 2005** in an envelope as "Express Mail Post Office to Addressee" Mail Label number **EL980001259US** addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Adriane Giberson
Name of person mailing paper

Date: June 22, 2005

Signature of person signing paper